

# Decision Memo for Serum Iron Studies (Expansion of the Chronic Renal Failure Covered Codes to Include Hypertensive Renal Disease) (CAG-00194N)

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## Decision Summary

CMS has determined that ICD-9-CM codes 403.01, 403.11, 403.91, 404.02, 404.03, 404.12, 404.13, 404.92, and 404.93 flow from the existing narrative for conditions for which serum iron testing is reasonable and necessary. We intend to modify the NCD for serum iron studies to include these codes in the list of ICD-9-CM codes covered by Medicare for this service.

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## Decision Memo

**This decision memorandum does not constitute a national coverage determination (NCD). It states the intent of the Centers for Medicare & Medicaid Services (CMS) to issue an NCD. Prior to any new or modified policy taking effect, CMS must first issue a manual instruction, program memorandum, CMS ruling or Federal Register Notice giving specific directions to our claims-processing contractors. That issuance, which includes an effective date, is the NCD. If appropriate, the Agency must also change billing and claims processing systems and issue related instructions to allow for payment. The NCD will be published in the Medicare Coverage Issues Manual or Program Memorandum. Policy changes become effective as of the date listed in the transmittal that announces the Coverage Issues Manual revision or Program Memorandum.**

To: Administrative File: CAG-00194N Serum Iron Studies (Expansion of the Chronic Renal Failure Covered Codes to Include Hypertensive Renal Disease)

From:

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Re: Decision Memorandum for Serum Iron Studies

Date: October 30, 2003

## **I. Decision**

CMS has determined that ICD-9-CM codes 403.01, 403.11, 403.91, 404.02, 404.03, 404.12, 404.13, 404.92, and 404.93 flow from the existing narrative for conditions for which serum iron testing is reasonable and necessary. We intend to modify the NCD for serum iron studies to include these codes in the list of ICD-9-CM codes covered by Medicare for this service.

## **II. Background**

On July 3, 2003 CMS began a national coverage determination process for expansion of ICD-9-CM codes for renal failure with regard to the serum iron studies NCD. Serum iron studies are useful in the evaluation of disorders of iron metabolism, particularly iron deficiency and iron excess. Iron deficiency is the most common cause of anemia. In adults, iron deficiency is usually the result of blood loss and is only occasionally secondary to dietary deficiency or malabsorption. Serum iron may also be altered in acute and chronic inflammatory and neoplastic conditions. Serum iron studies include the assessment of ferritin, iron, iron binding capacity and transferrin.

Patients with chronic renal failure frequently also suffer from anemia. Erythropoietin, which is necessary for the body to make red blood cells needed to carry oxygen throughout the body, is produced by the kidneys. Thus, patients with kidney failure have little to no naturally occurring erythropoietin. Erythropoietin therapy requires appropriate iron stores to work efficiently. End stage renal disease patients are routinely monitored to ensure that red blood cells and iron stores are adequate to manage anemia.

## **III. History of Medicare Coverage**

In accordance with section 4554 of the Balanced Budget Act of 1997, CMS entered into negotiations with the laboratory community regarding coverage and administrative policies for clinical diagnostic laboratory services. As part of these negotiations, we promulgated a rule that included 23 NCDs. One of these NCDs was for serum iron studies. The rule was proposed in the March 10, 2000 edition of the Federal Register (65 FR 13082) and was made final on November 23, 2001 (66 FR 58788). The final rule called for a 12-month delay in effectuating the NCDs in accordance with the recommendations of the negotiating committee. Thus, the NCDs became effective on November 25, 2002.

In the laboratory NCDs, CMS determined that coverage of specific tests were reasonable and necessary for certain medical indications. These decisions were evidence-based, relying on scientific literature reviewed by the negotiating committee. The NCDs contain a narrative describing the indications for which the test is reasonable and necessary. We also developed a list of ICD-9-CM codes that designate diagnoses/conditions that fit within the narrative description of indications that support the medical necessity of the test. This list is entitled "ICD-9-CM codes covered by Medicare," and includes codes where there is a presumption of medical necessity.

In addition, we developed two other ICD-9-CM code lists. The second list is entitled "ICD-9-CM codes denied," and lists diagnosis codes that are never covered by Medicare. The third list is entitled "ICD-9-CM codes that do not support medical necessity," and includes codes that generally are not considered to support a decision that the test is reasonable and necessary, but for which there are limited exceptions. Tests in this third category may be covered when they are accompanied by additional documentation that supports a determination of reasonable and necessary. We determined in the serum iron studies NCD that any ICD-9-CM code not listed in either of the ICD-9-CM covered or not covered sections would be categorized into this group that does not support medical necessity.

#### **IV. Timeline of Recent Activities**

As mentioned above, on March 10, 2000, CMS published a Notice of Proposed Rulemaking (NRPM) in the Federal Register (65 FR 13082). As an addendum to this NPRM, we proposed the 23 NCDs as negotiated by the rulemaking committee for public comment. On November 23, 2001, we published a final rule for coverage and administrative policies for clinical diagnostic laboratory services (66 FR 58788). The serum iron studies NCD included the ICD-9-CM codes 585 and 586 for renal failure chronic and unspecified, respectively, in the list of ICD-9-CM codes covered by Medicare.

On May 27, 2003, we received a formal NCD request from Sharon Mills at Baptist Memorial Health Care regarding renal failure. Ms. Mills noted that ICD-9-CM coding rules require the use of hypertensive renal disease codes to report renal failure that is caused by hypertension. These codes are not listed in the Medicare covered list. She requested the addition of the following codes to the serum iron studies NCD: 403.01, Hypertensive renal disease, malignant, with renal failure; 403.11, Hypertensive renal disease, benign, with renal failure; 403.91, Hypertensive renal disease, unspecified, with renal failure; 404.02, Hypertensive heart and renal disease, malignant, with renal failure; 404.03, Hypertensive heart and renal disease, malignant, with heart and renal failure; 404.12, Hypertensive heart and renal disease, benign, with renal failure; 404.13, Hypertensive heart and renal disease, benign, with heart and renal failure; 404.92, Hypertensive heart and renal disease, unspecified, with renal failure; and, 404.93, Hypertensive heart and renal disease, unspecified, with heart and renal failure.

On July 3, 2003 we announced in a tracking sheet posted on the Medicare coverage Internet site (<http://www.cms.hhs.gov/mcd/viewtrackingsheet.asp?id=99>) that we were considering adding the codes for hypertensive renal failure to the list of covered codes for serum iron studies and solicited public comments during a 30-day period. At the end of the public comment period, August 4, 2003, we had not received any comments.

## **V. FDA Status**

Not Applicable

## **VI. General Methodological Principles**

During the negotiation meetings that led to the development of the 23 clinical diagnostic laboratory NCDs, we stated our intent that the narrative of the NCDs reflect the substance of the determinations. The addition of the coding lists was intended as a convenience to the laboratories and as a means of ensuring consistency among the Medicare claims processing contractors as they interpreted the narrative conditions that support coverage.

We reiterated this position in the November 23, 2001 final rule (66 FR 58795) in responding to public comments requesting the addition of numerous codes to the NCDs. That is, we stated that:

"It is critical that the narrative indications for the proposed policy and the ICD-9-CM codes that support medical necessity be consistent. Thus, in order for us to add codes to the list of ICD-9-CM codes that support medical necessity, those codes must either be determined to be an appropriate translation of an existing indication, or we must add a new indication for the test in the policy narrative."

Further, in Program Memorandum AB 02-110 we stated our intent as follows:

"The codes included in the NCDs are intended to flow exclusively from the narrative of the NCDs. Therefore, requests for the addition of primary diagnosis codes must include rationale demonstrating the provision of the narrative that supports the inclusion of the code or scientific evidence supporting the inclusion of the condition to the narrative portion of the NCD. Clerical maintenance of the coding lists will be made without following the NCD process. Clerical maintenance may include such actions as revision of codes to be consistent with the annual CPT and ICD-9-CM coding updates, expansion of codes to full range of digits, and correction of code errors that may exist."

## **VII. CMS Analysis**

As noted above, we have taken the position that the ICD-9-CM Codes Covered by Medicare list are intended to contain only those codes that flow from the narrative of the indication in the NCD. The serum iron studies NCD lists the following as an indication for testing:

4. Serum ferritin may be appropriate for monitoring iron status in patients with chronic renal disease with or without dialysis.

We believe that the ICD-9-CM codes for chronic renal disease for patients with renal failure caused by hypertension include the following codes:

403.01, Hypertensive renal disease, malignant, with renal failure  
403.11, Hypertensive renal disease, benign, with renal failure  
403.91, Hypertensive renal disease, unspecified, with renal failure  
404.02, Hypertensive heart and renal disease, malignant, with renal failure  
404.03, Hypertensive heart and renal disease, malignant, with heart and renal failure  
404.12, Hypertensive heart and renal disease, benign, with renal failure  
404.13, Hypertensive heart and renal disease, benign, with heart and renal failure  
404.92, Hypertensive heart and renal disease, unspecified, with renal failure  
404.93, Hypertensive heart and renal disease, unspecified, with heart and renal failure

These codes flow from the existing narrative indications statement that includes chronic renal disease. Consequently, we intend to issue an NCD to add the above codes to the list of the ICD-9-CM codes covered for serum iron studies.

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